

Application No.: 10/727,292

Docket No.: JCLA12308-R

REMARKS**Present Status of the Application**

The Office Action mailed November 29, 2005 rejected all pending claims 1, 2 & 7-11. Specifically, claims 1, 7 & 9 were rejected under 35 USC 102(b) as being anticipated by Mizutani (JP10-298175), and claims 1-2 and 7-11 were rejected under 35 USC 103(a) as being unpatentable over Mizutani, Bryan et al. (US 5,994,508, Bryan) and Obata et al. (US 6,444,239, Obata). In response thereto, Applicants have further amended claim 1, and have amended claims 7-8 and canceled claims 9-10 for the amendments of claim 1.

It is noted that the first amendment (without addition of solubilizing agents) of claim 1 is supported by paragraph [0005] of the specification and the second one (wherein...without a physical treatment) is previously in canceled claims 9-10. Hence, *no new matter is raised with the amendments*. Reconsideration of claims 1-2, 7-8 and 11 is respectfully requested.

Discussion for Amendments to Title and Specification

Please note that the words “composition containing soluble isoflavones” in the title, specification and claims have been replaced with “soluble composition containing isoflavones”. This amendment does not raise new matter but makes the subject matter of this invention more correct in the physical/chemical sense, because the isoflavones *themselves* are still the same low-solubility materials as before and it is the isoflavone-containing composition that is soluble.

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Discussion of Rejections under 35 USC 102(b)

Claims 1, 7 & 9 were rejected under 35 USC 102(b) as being anticipated by Mizutani. Please note that Applicants have amended claims 1 & 7 and canceled claim 9. Applicants believe that the amendments can overcome the rejections to claims 1 and 7.

One feature of amended claim 1 is that the soybean extract liquid is obtained from a soybean material *without* a physical treatment and prepared *without* addition of solubilizing agents. Mizutani fails to disclose the feature, because his soybean extract liquid is obtained from the soybean material *with* a pulverization treatment (paragraph [0013]) as a physical treatment and then added *with* cyclodextrin as a solubilizing agent.

For at least the above reasons, Applicants respectfully submit that amended claim 1 patentably defines over the prior art.

For at least the same reasons mentioned above, Applicants respectfully submit that claim 7 dependent from claim 1 also patentably defines over the prior art.

Discussion of Rejections under 35 USC 103(a)

Claims 1-2 & 7-11 were rejected under 35 USC 103(a) as being unpatentable over Mizutani, Bryan and Obata. Please note that Applicants have amended claims 1 & 7-8 and canceled claims 9-10. Applicants believe that the above amendments to claim 1 can overcome the rejections, because at least the above feature of amended claim 1 is non-obvious over the prior art for at least the following reasons.

Firstly, none of Mizutani, Bryan and Obata discloses the above feature of claim 1. Mizutani fails to disclose the feature, as mentioned above. Bryan or Obata also fails to

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disclose the feature, because Bryan or Obata obtains the soybean extract liquid from the soybean material *with* a physical treatment.

As described in col. 4, lines 23-25, Bryan's starting material for the soybean extract liquid is soy flakes, soy meal or soy flour, *which is surely obtained from a soybean material with a physical treatment* like slicing or grinding.

As for Obata, as described in Examples 1-3 in columns 4 and 5 thereof, a soybean material (defatted soybeans) is *ground* and extracted to obtain a soybean extract liquid. The grinding treatment is surely a physical treatment.

Secondly, the above feature of claim 1 cannot be obtained by combining the three cited references at least because

- 1) Mizutani, Bryan or Obata obtains a soybean extract liquid with a physical treatment,
- 2) Mizutani as the major reference stresses many drawbacks of not adding solubilizing agents to the soybean extract liquid, especially the drawback of the low solubility of isoflavones, in the background part, therefore *teaching away* to extract isoflavones without addition of solubilizing agents, and
- 3) Mizutani teaches to use cyclodextrin (CD) as a solubilizing agent while Bryan or Obata does not teach away the use of a solubilizing agent, so that even the feature of not adding solubilizing agents cannot be obtained by combining the three references.

Moreover, the method of amended claim 1 is not a trivial modification or a simple optimization of the prior art. It is noted that the Office Action mentioned that Mizutani extracts isoflavones at pH=2-8 and 5-40°C. However, Mizutani made his experiments only at pH=5 and 20°C (Examples 1 and 2), but never noticed that a higher pH of 5.5-7

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and a lower temperature of 0-17°C as set in the method of claim 1 are much better for the centrifugal separation of the insoluble materials *so that CD as a solubilizing agent can be saved*. Differently, the method of amended claim 1 with the higher pH and lower temperature allows the insoluble materials to be formed and separated more readily, so that the isoflavones is effectively solublized even without addition of solubilizing agents.

Mizutani also teaches, in Examples 1-2 (paragraphs [0035] and [0036]), that *when CD is used* in isoflavone extraction, the extraction liquid is treated (with Diaion HP-20, an adsorbent from Mitsubishi Chemical Co.) in advance to form a composition containing isoflavones in a higher purity, so that the extraction operation is complicated as compared with the method of claim 1. Moreover, for the solubility of CD is limited, the isoflavone cannot be dissolved in a high concentration in Examples 1-2 as in the method of claim 1. As described in paragraph [0025] of Mizutani, the isoflavone solubility made with his method is merely 0.01-0.45g (in 100ml of water). As describe in paragraph [0022] of the specification of this invention, however, the isoflavone solubility made with the method of this invention can be as much as 0.3-100g (in 100g [≈100ml] of water at 25°C).

Moreover, Mizutani teaches to pulverize the soybean hypocotyl in the process of obtaining the soybean extracted liquid in paragraph [0013]. However, as indicated by paragraph [0010] of the specification of this invention, if the soybean cells are destroyed in a physical treatment like pulverization, much protein or lipid is also extracted so that a clear isoflavone-dissolved composition is not obtained through centrifugal separation, and the amount of the insoluble materials is large as the soybean extract liquid is cooled so that more isoflavones are lost as co-precipitating with the insoluble materials.

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Briefly speaking, this invention discovered that by omitting a physical treatment and solubilizing agents as well as removing the insoluble materials from the soybean extract liquid at specific pH and temperature ranges, a soluble composition having a much higher isoflavone concentration as compared with that obtained from Mizutani's method can be obtained. Such an effect cannot be known by referring to Mizutani that teaches to perform a physical treatment to the soybean hypocotyls and add CD as a solubilizing agent to the soybean extract liquid.

Accordingly, the method of amended claim 1 is difficult to think of based on the teaching of Mizutani or based on the combination of Mizutani with Bryan and Obata, which two set the pH value outside the range (5.5-7) of claim 1 and also perform a physical treatment to the soybean material for obtaining a soybean extract liquid.

For at least the above reasons, Applicants respectfully submit that amended claim 1 patently defines over the prior art.

For at least the same reasons mentioned above, Applicants respectfully submit that claims 2, 7-8 and 11 dependent from claim 1 also patently define over the prior art.

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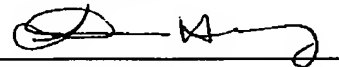
CONCLUSION

For at least the foregoing reasons, it is believed that pending claims 1-2, 7-8 and 11 are in proper condition for allowance. If the Examiner believes that a telephone conference would expedite the examination of the above-identified patent application, the Examiner is invited to call the undersigned.

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